



FEB 09 2011

The Honorable Edward J. Markey
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Markey:

Thank you for your letter of December 22, 2010, requesting an update on the Food and Drug Administration's (FDA or the Agency) efforts to finalize its regulation of over-the-counter (OTC) topical antiseptic drug products, including certain soaps and hand sanitizers.

In our February 23, 2010, letter to you, we discussed the Agency's ongoing scientific and regulatory review of the safety and effectiveness of triclosan and triclocarban in FDA-regulated drug products. FDA is working to complete the OTC Drug Review in the face of complex, evolving science, and is actively collaborating with other federal agencies to develop the scientific understanding we need to determine whether triclosan and triclocarban meet the standard of general recognition of safety and effectiveness.

New data and information available to FDA after 1994, but particularly since 2005, pertain to at least five separate complex scientific issues: (1) antimicrobial and antibiotic resistance; (2) endocrine disruption; (3) increased exposure to consumer antimicrobial products, new dosage forms, and changes in use patterns; (4) the appropriate effectiveness standard for consumer antiseptic drug products; and (5) increased environmental exposure to antiseptic products. New data and information affecting these products and their ingredients, including triclosan and triclocarban, are continually emerging, and FDA is working to incorporate that data and information into the monographs. FDA will communicate the findings of its review to the public as soon as practicable.

In April 2010, in an effort to keep the public aware of the status of FDA's review of triclosan, FDA updated its website, www.fda.gov/ForConsumers/ConsumerUpdates/ucm205999.htm, with information about triclosan. In our update, we provided consumers current information regarding triclosan, including information on its safety and benefit in consumer products. We are enclosing a copy for your convenience.


Additionally, we are aware of the scientific studies that were noted in your letter and will take these data into consideration when making our final decision.

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Thank you for your interest in this important matter. Please let us know if you have any further questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michelle Nital".

 for Jeanne Ireland
Assistant Commissioner
for Legislation

Enclosure

Triclosan: What Consumers Should Know

What is triclosan?

Triclosan is an ingredient added to many consumer products to reduce or prevent bacterial contamination. It may be found in products such as clothing, kitchenware, furniture, and toys. It also may be added to antibacterial soaps and body washes, toothpastes, and some cosmetics—products regulated by the U.S. Food and Drug Administration (FDA).

What is known about the safety of triclosan?

Triclosan is not currently known to be hazardous to humans. But several scientific studies have come out since the last time FDA reviewed this ingredient that merit further review.

Animal studies have shown that triclosan alters hormone regulation. However, data showing effects in animals don't always predict effects in humans. Other studies in bacteria have raised the possibility that triclosan contributes to making bacteria resistant to antibiotics.

In light of these studies, FDA is engaged in an ongoing scientific and regulatory review of this ingredient. FDA does not have sufficient safety evidence to recommend changing consumer use of products that contain triclosan at this time.

Does triclosan provide a benefit in consumer products?

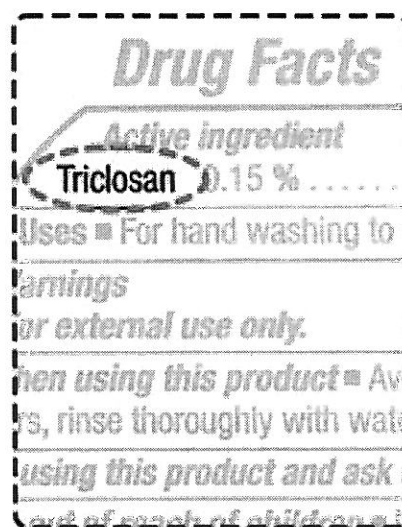
For some consumer products, there is clear evidence that triclosan provides a

benefit. In 1997, FDA reviewed extensive effectiveness data on triclosan in Colgate Total toothpaste. The evidence showed that triclosan in this product was effective in preventing gingivitis.

For other consumer products, FDA has not received evidence that the triclosan provides an extra benefit to health. At this time, the agency does not have evidence that triclosan in antibacterial soaps and body washes provides any benefit over washing with regular soap and water.

What consumers should know:

- Triclosan is not known to be hazardous to humans.
- FDA does not have sufficient safety evidence to recommend changing consumer use of products that contain triclosan at this time.
- In light of questions raised by recent animal studies of triclosan, FDA is reviewing all of the available evidence on this ingredient's safety in consumer products. FDA will communicate the findings of its review to the public in spring 2011.
- At this time, FDA does not have evidence that triclosan added to antibacterial soaps and body washes provides extra health benefits over soap and water. Consumers concerned about using hand and body soaps with triclosan should wash with regular soap and water.
- Consumers can check product labels to find out whether products contain triclosan.



How can I tell if there is triclosan in a product that I am using?

Antibacterial soaps and body washes, and toothpastes are considered over-the-counter drugs. If an over-the-counter drug contains triclosan, it will be listed as an ingredient on the label, in the Drug Facts box. If a cosmetic contains triclosan, it will be included in the ingredient list on the product label.

What is FDA doing to evaluate the safety of triclosan?

We are engaged in an ongoing scientific and regulatory review of the safety of triclosan in FDA-regulated products. We also have partnered with other Federal Agencies to study the effects of this substance on animal and environmental health (see www.epa.gov/oppsrrd1/REDs/factsheets/triclosan_fs.htm and www.epa.gov/endo/).

FDA is working to incorporate the most up-to-date data and information into the regulations that govern the use of triclosan in consumer products. FDA will communicate the findings of its review to the public in spring 2011.

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